

FORM PTO-1390 (Modified) U.S. PATENT AND TRADEMARK OFFICE; U.S. DEPARTMENT OF COMMERCE  
(REV. 2-2005)

ATTORNEY'S DOCKET NUMBER

277219US0PCT

**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A SUBMISSION UNDER 35 U.S.C. 371**

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

**10/549763**

INTERNATIONAL APPLICATION NO.  
PCT/EP04/50286

INTERNATIONAL FILING DATE  
11 March 2004

PRIORITY DATE CLAIMED  
18 March 2003

**TITLE OF INVENTION**

**LIQUID GROWTH HORMONE FORMULATION AND PROCESS OF PREPARATION THEREOF**

**APPLICANT(S) FOR DO/EO/US**

**Piergiorgio DONATI et al.**

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

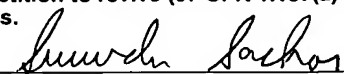
1. ☒ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.
4. ☒ The US has been elected (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
  - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☒ has been communicated by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a. ☐ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☒ A copy of the International Search Report (PCT/ISA/210).

**Items 13 to 23 below concern document(s) or information included:**

13. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☒ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A power of attorney and/or change of address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
20. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4).
22. ☐ Express Mail Label No.
23. ☒ Other items or information:

Application Data Sheet/Notice of Priority/PCT/IB/304/  
Cited References (32)/PTO-1449/Statement of Relevancy

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. (If known, see 37 CFR 1.53) <b>10/349763</b>		INTERNATIONAL APPLICATION NO. <b>PCT/EP04/50286</b>		ATTORNEY'S DOCKET NUMBER <b>277219US0PCT</b>	
The following fees are submitted:				<b>CALCULATIONS</b>	<b>PTO USE</b>
24. <input checked="" type="checkbox"/> Basic national fee		\$300	\$	\$300.00	
25. <input checked="" type="checkbox"/> Examination fee					
If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4).			\$100	\$	\$200.00
All other situations.			\$200		
26. <input checked="" type="checkbox"/> Search fee					
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority			\$100		
International Search Report prepared and provided to the Office			\$400		
All other situations.			\$500	\$	\$400.00
<b>TOTAL OF 24, 25 and 26 =</b>				\$	\$900.00
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole)	RATE		
- 100 =	0 /50 =	0	x \$250.00	\$	\$0.00
Surcharge of \$130.00 for furnishing the oath or declaration later than months from the earliest claimed priority date (37 CFR 1.492(e)).				\$	\$130.00
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	29 - 20 =	9	x \$50.00	\$	\$450.00
Independent claims	1 - 3 =	0	x \$200.00	\$	\$0.00
MULTIPLE DEPENDENT CLAIMS (if applicable) <input type="checkbox"/> +			\$360.00	\$	\$0.00
<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$	\$1,480.00
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$	\$0.00
<b>SUBTOTAL =</b>				\$	\$1,480.00
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$	\$0.00
<b>TOTAL NATIONAL FEE =</b>				\$	\$1,480.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property +				\$	\$0.00
<b>TOTAL FEES ENCLOSED =</b>				\$	\$1,480.00
				Amount to be	\$
				Amount to be	\$
<p>a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed.</p> <p>b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of _____ to cover the above fees. A duplicate copy of this sheet is enclosed.</p> <p>c. <input checked="" type="checkbox"/> The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>15-0030</u>. A duplicate copy of this sheet is enclosed.</p> <p>d. <input checked="" type="checkbox"/> Fees are to be charged to a credit card. <b>WARNING:</b> Information on this form may become public. <b>Credit card information should not be included on this form.</b> Provide credit card information and authorization on PTO-2038.</p> <p><b>NOTE:</b> Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.</p> <p>SEND ALL CORRESPONDENCE TO:</p> <p>Customer Number 22850</p> <p style="text-align: center;">Surinder Sachar Registration No. 34,423</p> <p style="text-align: right;">               SIGNATURE              Richard L. Treanor              NAME              36,379              REGISTRATION NUMBER           </p>					

10/549763

Docket No. 277219US0PCT

IN RE APPLICATION OF: Piergiorgio DONATI, et al.

J035 Rec'd PCT/PTO 19 SEP 2005

SERIAL NO: New U.S. PCT Application Based on PCT/EP04/50286

FILED: Herewith

FOR: LIQUID GROWTH HORMONE FORMULATION AND PROCESS OF PREPARATION THEREOF

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

SIR:

Transmitted herewith is an amendment in the above-identified application.

☒ No additional fee is required☐ Small entity status of this application under 37 C.F.R. §1.9 and §1.27 is claimed.☒ Additional documents filed herewith: Credit Card Payment Form for \$1,480.00/PCT Transmittal Letter/Application Data Sheet/Notice of Priority/Preliminary Amendment/PCT/IB/304/International Search Report/Information Disclosure Statement/PTO-1449/Cited References (32)/Statement of Relevancy

The Fee has been calculated as shown below:

CLAIMS	CLAIMS REMAINING		HIGHEST NUMBER PREVIOUSLY PAID	NO. EXTRA CLAIMS	RATE	CALCULATIONS
TOTAL	29	MINUS	29	0	x \$50 =	\$0.00
INDEPENDENT	1	MINUS	1	0	x \$200 =	\$0.00
		<input type="checkbox"/> MULTIPLE DEPENDENT CLAIMS			+ \$360 =	\$0.00
		TOTAL OF ABOVE CALCULATIONS				\$0.00
		<input type="checkbox"/> Reduction by 50% for filing by Small Entity				\$0.00
		<input type="checkbox"/> Recordation of Assignment			+ \$40 =	\$0.00
		TOTAL				\$0.00

☐ A check in the amount of \$0.00 is attached.☐ Credit card payment form is attached to cover the fees in the amount of \$0.00☒ Please charge any additional Fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to deposit Account No. 15-0030. A duplicate copy of this sheet is enclosed.☒ If these papers are not considered timely filed by the Patent and Trademark Office, then a petition is hereby made under 37 C.F.R. §1.136, and any additional fees required under 37 C.F.R. §1.136 for any necessary extension of time may be charged to Deposit Account No. 15-0030. A duplicate copy of this sheet is enclosed.OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.

Richard L. Treanor

Registration No. 36,379

Customer Number

22850

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Fax. (703) 413-2220  
(OSMMN 05/03)Surinder Sachar  
Registration No. 34,423